

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA,

Plaintiff,

v.

BAYER CORPORATION

Defendant.

Case No. 2:07-cv-00001

(Hon. Jose L. Linares)

(Hon. Joseph. A. Dickson)

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**DEFENDANT'S PROPOSED FINDINGS OF FACT
AND CONCLUSIONS OF LAW**

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TABLE OF CONTENTS

TABLE OF AUTHORITIES..... iv

I. Findings Of Fact 1

 A. Background 1

 B. Regulatory Framework 2

 C. Procedural History 5

 D. Product: Phillips’ Colon Health..... 6

 E. Claims at Issue 6

 F. Bayer’s Review Process..... 10

 G. Scientific Substantiation for PCH 13

 H. Government’s Evidence 18

 I. Bayer’s Experts 21

II. Conclusions of Law 26

 A. Standard of Review 26

 B. Bayer Made Stucture-Function Claims, Not Disease Claims..... 27

 i. The Express Claims Made for PCH Are Structure-Function
 Claims 27

 ii. There Are No Implied Disease Claims Made for PCH..... 29

 C. Bayer Was Not Provded With Any Notice That The Consent Decree
 Requires a Laine-Level RCT..... 32

 D. Dr. Laine’s Testimony Does Not Satisfy the Government’s Burden..... 36

 E. Bayer Possessed and Relied Upon Competent and Reliable Scientific
 Evidence 42

 i. Bayer Possessed and Relied Upon Evidence From The Public
 Domain, As Well As Proprietary Data..... 42

ii. Bayer’s Evidence Satisfies the Competent and Reliable Scientific
Evidence Standard 46

F. Bayer Substantially Complied 49

CONCLUSION 50

TABLE OF AUTHORITIES

	Page
CASES	
<i>Basic Research, LLC v. FTC</i> , No. 2:09-cv-0779 (D. Utah Nov. 25, 2014).....	32
<i>California v. Trombetta</i> , 467 U.S. 479 (1984)	44
<i>Ford v. Kammerer</i> , 450 F.2d 279 (3d Cir. 1971).....	26, 32
<i>Fox v. Capital Co.</i> , 96 F.2d 684 (3d Cir. 1938).....	26
<i>FTC v. Garden of Life, Inc.</i> , 845 F. Supp. 2d 1328 (S.D. Fla. 2012), <i>aff'd in part and vacated in part</i> , 516 F. App'x 852 (11th Cir. 2013)	32
<i>FTC v. Lane Labs-USA, Inc.</i> 21, 624 F.3d 575 (3d Cir. 2010).....	33, 49
<i>Harris v. City of Phila.</i> , 47 F.3d 1342 (3d Cir. 1995).....	26, 32, 33
<i>Harris v. City of Phila.</i> , 137 F.3d 209 (3d Cir. 1998).....	27, 32
<i>Merkle v. Upper Dublin Sch. Dist.</i> , 211 F.3d 782 (3d Cir. 2000).....	44
<i>In re Unisys Corp. Long-Term Disability Plan ERISA Litig.</i> , 97 F.3d 710 (3d Cir. 1996).....	43
<i>United States v. New Jersey</i> , 194 F.3d 426 (3d Cir. 1999).....	26, 27, 36, 43
<i>United States v. Valenzuela-Bernal</i> , 458 U.S. 858 (1982)	44

Whiteley v. Warden,
401 U.S. 560 (1971) 43

STATUTES AND REGULATIONS

Dietary Supplement Health & Education Act of 1994, Pub. L. No. 103-417,
108 Stat. 4325 (codified at 21 U.S.C. § 350(b))passim

21 U.S.C. § 321(ff) 2

21 U.S.C. § 331(d)..... 2

21 U.S.C. § 343(r)(6).....2, 9, 28, 38

21 U.S.C. § 355(a) 2

21 C.F.R. § 314.126 2

65 Fed. Reg. 1000 (Jan. 6, 2000)passim

OTHER AUTHORITIES

American Heritage College Dictionary (4th ed. 2002)..... 43

American Heritage Dictionary (5th ed. 2013) 43

Random House Webster’s Unabridged Dictionary (2d ed. 2001)..... 43

Webster’s Third New International Dictionary (1993) 43

FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under
Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act* (Dec. 2008),
[http://www.fda.gov/food/guidanceregulation/
guidancedocumentsregulatoryinformation/dietarysupplements/
ucm073200.htm](http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm) 4-5

I. Findings of Fact

A. Background

1. On January 3, 2007, the United States of America (“the United States” or “the Government”) and Bayer Corporation (“Bayer”) entered into a consent decree (“Consent Decree”). *See* Dkt. No. 2; DX-1.

2. On September 12, 2014, alleging violations of this Consent Decree, the United States filed a motion for an order to show cause why Bayer should not be held in contempt (“contempt motion”). Dkt. No. 4.

3. The Government’s contempt motion alleged a violation of Section III of the Consent Decree, which requires Bayer to “possess[] and rel[y] upon competent and reliable scientific evidence that substantiates” any dietary supplement claim. Dkt. No. 2 at 5. In its trial brief, Dkt. No. 158, the Government cited another provision of the decree, the recordkeeping provision, but has since disclaimed that this provision is an “independent ground[] for the contempt motion.” Tr. 1.11:3-10 (government opening statement).

4. The Consent Decree defines “competent and reliable scientific evidence” as “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” Dkt. No. 2 at 2.

B. Regulatory Framework

5. Bayer's Consent Decree adopted the substantiation standard—"competent and reliable scientific evidence"—that applies to the entire industry through agency guidance promulgated under the Dietary Supplement Health & Education Act of 1994 (DSHEA), Pub. L. No. 103-417, sec. 8, § 413(c) (codified at 21 U.S.C. § 350(b)); *see* PX-1 *Dietary Supplements: An Advertising Guide for Industry* at 3 ("FTC Guidance").

6. Recognizing the health benefits of dietary supplements, Congress enacted DSHEA to ensure that supplements can be marketed and sold without following the stringent requirements imposed on drugs. Although new drugs must be pre-approved by the Food and Drug Administration, *see id.* § 331(d); *id.* § 355(a), and traditionally must be supported by randomized, placebo-controlled, double-blind clinical trials, *see* 21 C.F.R. § 314.126, dietary supplements need not.

7. For dietary supplements, the only substantiation requirement is that claims must be "truthful and not misleading." 21 U.S.C. § 343(r)(6)(B); *see also id.* § 321(ff) (defining "dietary supplement" as any non-tobacco product "intended to supplement the diet"); *id.* § 343(r)(6)(A) (identifying types of dietary supplement claims, including structure/function claims). As long as the supplement is not marketed as a drug—*i.e.*, it is "not claim[ed] to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," *id.* § 343(r)(6); *id.* § 343(r)(6)(C) (requiring disclaimer)—it is not regulated like a drug.

8. DSHEA does not specify what substantiation is necessary to render a claim “truthful and not misleading.” Accordingly, in April 2001, the Federal Trade Commission provided guidance, stating that the relevant standard is “competent and reliable scientific evidence.” See PX-1 *Dietary Supplements: An Advertising Guide for Industry* at 3 (“FTC Guidance”).

9. The FTC Guidance defines “competent and reliable scientific evidence” to mean: “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” *Id.* at 9.

10. The FTC Guidance and Consent Decree therefore use the same definition of “competent and reliable scientific evidence” (with the exception of a typographical error). DX-278 No. 1 (Governments’ Amended Response to Bayer’s Requests for Admission).

11. The FTC Guidance provides additional scientific and medical guidance regarding the evidence necessary to meet the “competent and reliable scientific evidence” standard embodied in both the FTC Guidance and Bayer’s Consent Decree. PX-1.

12. First, the FTC Guidance makes clear that this standard is *not* the drug standard. Randomized clinical trials are *not* required. FTC Guidance at 9-18. Instead, “competent and reliable scientific evidence” is a “flexible” standard, and “[t]here is *no*

fixed formula for the number or type of studies required.” *Id.* at 8-9 (emphasis added). Although “well-controlled human clinical studies are the most reliable form of evidence[,]” they are not necessary, and “[r]esults obtained in animal and in vitro studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible.” *Id.* at 10 (emphasis added). “[R]esearch explaining the biological mechanism underlying the claimed effect” will also be considered. *Id.* “[E]pidemiologic evidence may be an acceptable substitute for clinical data” in some circumstances. *Id.*

13. Second, the FTC Guidance states that one should look to “the totality of the evidence.” *Id.* at 14 (capitalization omitted). “The surrounding body of evidence will have a significant impact both on what type, amount and quality of evidence is required to substantiate a claim and on how that claim is presented.” *Id.*

14. Third, studies on the precise formula used in the advertised product are not required. Rather, it can be “appropriate to extrapolate from the research to the claimed effect,” even if there “are significant discrepancies between the research conditions and the real life use being promoted.” *Id.* at 16.

15. The Food and Drug Administration (FDA) agrees in its guidance, recognizing that randomized, controlled clinical trials for dietary supplements may not be “possible, practical, or ethical.” See FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act* (Dec. 2008), <http://www.fda.gov/food/guidanceregulation>

/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm

(“FDA Guidance”).

C. Procedural History

16. In 2011, the FTC began investigating Bayer’s marketing of Phillips Colon Health (“PCH”), a probiotic dietary supplement. *See* Dkt. No. 4-1 at 3.

17. In response to the Government’s investigation, Bayer produced nearly 100 scientific articles that supported its advertising claims for PCH. *See* June 15-30, 2015 Evid. Hr’g Tr. (“Tr.”) 3.39:7-17; DX-254 (Sept. 30, 2013 Letter from M. Davis to L. Laine) at 4.

18. On September 12, 2014, the United States filed its contempt motion. In this motion, for the first time, the Government disclosed the existence of its expert, Dr. Loren Laine, and the study design which he opined was required to provide competent and reliable scientific evidence. Dkt. No. 4-8; PX-160.

19. Specifically, Dr. Laine opined that “competent and reliable scientific evidence” could only be met through “human clinical trials that (1) are randomized, placebo-controlled, and double-blind; (2) use the specific product for which the claims are made; (3) are performed in the population at which the claims are directed; and (4) use validated methods and appropriate statistical methods to assess ‘outcomes.’” Dkt. No. 4-1 at 16; *see also* PX-160 (“Laine-Level RCTs”).

20. On October 23, 2014, the Court directed Bayer to show cause why it did not violate the Consent Decree's requirement to "possess 'competent and reliable scientific evidence'" for dietary supplement claims. Dkt. No. 47 at 2.

21. Following further briefing and discovery, this Court held a seven-day evidentiary hearing that took place from June 15, 2015 until June 30, 2015.

D. Product: Phillips' Colon Health

22. Bayer launched its probiotic supplement PCH in 2008. Tr. 1.108:21-24, 1.130:18-21.

23. "Probiotics are live microorganisms that, when administered in sufficient amounts, may improve health." DX-5 at 3.

24. PCH contains three types of good bacteria: *Lactobacillus gasseri* KS-13, *Bifidobacterium bifidum* G9-1, and *Bifidobacterium longum* MM2. Tr. 1.76:12-18.

25. Probiotics, including PCH, are "a very safe intervention" with no risk of harm and "no down side." Tr. 5.50:11-12. No study on the bacteria in PCH has shown any adverse effect. Tr. 5.50:8-9. "The past thinking and the current thinking in the field is [that probiotics, including the species in PCH,] are perfectly safe." Tr. 5.77:22-25; *see also* Tr. 6.49:17-22 ("[F]or generally healthy people taking [probiotics including the PCH species], there is almost no side effect.").

E. Claims at Issue

26. Bayer makes the following claims for PCH:

- "To Promote Overall Digestive Health"

- “Helps Defend Against Occasional Constipation, Diarrhea, Gas and Bloating”

See, e.g., PX-2; PX-3; PX-20; PX-21; PX-22; PX-29; PX-34; PX-125.

27. At trial, a Government witness agreed that “the digestive health claim is the same thing as the claim of relief, occasional constipation, diarrhea, gas and bloating.” Tr. 2.99:9-13. *See also* Tr. 5.14:17-23 (looking at the PCH package, Dr. Fennerty understands the claims at issue to be the “singular claim of promoting overall digestive health” by “defend[ing] against the occasional constipation, diarrhea, gas and bloating that an individual or patient may have.”); Tr. 6.9:22-6.10:2 (“gastrointestinal health” means “things like abdominal pain, diarrhea, constipation, gas, bloating, and straining.”).

28. A Government witness also agreed that all of Bayer’s labels and advertisements for PCH contain the FDA disclaimer stating: “This product is not intended to diagnose, treat, cure or prevent any disease.” *See, e.g.*, PX-2; Tr. 2.91:15-17; Tr. 2.93:2-4; *see also* Tr. 2.42:16-19 (Dr. Beke noted that “[Bayer] regulatory ensures that every product label, every advertising and every promotional material that makes a structure function claim[] has a DSHEA statement on that page facing and linked to the claim.”); PX-3; PX-7; PX-20; PX-29; PX-34; PX-125.

29. A Government witness testified that “[n]one of [PCH’s] advertisements show sick people.” Tr. 2.98:4-6. “None of [them] shows anyone suffering from a disease.” Tr. 2.98:7-9. Rather, they are humorous and lighthearted advertisements

that show healthy and active individuals. Tr. 2.98:10-20 (Government witness affirming that the advertisements “made [her] laugh”); PX-157, -158 (advertisement showing PCH spokesperson speaking to active and healthy individuals on a safari); PX-34, -41 (ad showing PCH spokesperson speaking to active and healthy individuals on an airplane); PX-23, -25 (ad showing PCH spokesperson speaking to active and healthy individuals at a book reading).

30. Bayer’s claims for PCH are all categorized as structure/function claims under FDA regulations. Tr. 2.16; Tr. 2.40:22-25; *see* 65 Fed. Reg. 1000, 1006 (Jan. 6, 2000) (“a claim that a product ‘helps promote digestion’ would be a structure/function claim because it does not refer explicitly or implicitly to an effect on a disease state”); *id.* at 1026 (“for relief of ‘occasional constipation’ should not be considered [a] disease claim[]”); *id.* at 1031 (stating that “[a]lleviates the symptoms referred to as gas” and “alleviates bloating” are structure/function claims “because the symptoms . . . are not sufficiently characteristic of specific diseases”); *see also id.* at 1033 (“‘helps maintain regularity’ is an acceptable structure/function claim”); *see also id.* at 1015, 1029.

31. Bayer does not make disease claims for PCH. The Government does not contend Bayer made disease claims, and a Government witness agreed that Bayer has “disclaim[ed]” any disease claim. Tr. 2.91:24; *see* PX-2; (FDA disclaimer stating: “This product is not intended to diagnose, treat, cure or prevent any disease”).

32. Bayer has submitted “30-day notification letters” to the Food and Drug Administration notifying the agency of its claims for PCH. Tr. 2.41:10-15. The FDA has not responded to or rejected any of Bayer’s FDA notifications regarding its claims. Tr. 2.41:16 – 2.42:6. If Bayer had made a disease claim for PCH, the FDA had authority to treat PCH as an unapproved drug subject to seizure and destruction under the Federal Food Drug and Cosmetic Act. 21 U.S.C. § 343(r)(6)(A).

33. The Government has suggested that Bayer made “implied” claims that PCH can help prevent, treat, or cure constipation, diarrhea, gas and bloating. Dkt. No. 4-1. (contempt motion) at 10. Government counsel conceded in closing that Bayer’s “ads don’t . . . use the terms ‘cure, prevent, and treat.’” Tr. 7.41:21-25. Nonetheless, counsel asserted that the terms Bayer does use “are clearly euphemisms for ‘treat, cure and prevent.’” *Id.* That suggestion is irrelevant because the Government has not argued that Bayer has made any *disease* claims (either explicitly or implicitly), and the packaging and all advertisements for PCH expressly state that PCH is “not intended to diagnose, treat, cure or prevent any disease.” *See, e.g.* PX-2; Tr. 2.91:15-17.

34. Moreover, these so-called “euphemisms” have been expressly permitted by the FDA. *See, e.g.*, 65 Fed. Reg. at 1006, 1015, 1026, 1029, 1031, 1033; *see also supra* at ¶ 30.

35. The Government presented no evidence that Bayer made implied claims of any kind, let alone implied disease claims. It presented no consumer survey

data, no customer impression testimony, and no expert marketing testimony of any kind. The suggestion of “implied” disease claims is contrary to the record and rests solely on the arguments of counsel.

36. Unlike other cases cited by the Government, the FTC made no agency findings that Bayer made any implied disease claims.

F. Bayer’s Review Process

37. To ensure that it complies with the Consent Decree, Bayer follows an extensive process known as the Legal, Medical, Regulatory (LMR) review. Tr. 2.34:6-8; Tr. 2.37:12-20; PX-73 (US-SOP-013-BPD); PX-74 (SOP-GRD-RA-201). LMR review and approval is required for every single piece of “promotional material” that “go[es] out the door as a public document.” Tr. 2.37:12-20.

38. The LMR process consists of one representative each from the Legal, Medical, and Regulatory groups. Tr. 2.34:14-22. A standard operating procedure guides this process and requires the submission of all advertisements and promotional materials to the LMR board for approval. PX-73 at 3. Before promotional material may be published, unanimous approval of the LMR group must be obtained. Tr. 2.37:5-11; *see also* Tr. 2.39:16-21. If any member of the LMR group does not agree that a piece of promotional material complies with legal, medical, and regulatory obligations, the material will not be published. PX-73 at 3; Tr. 2.37:18-21.

39. The LMR approval process is “ongoing” and applies to all “current and new products.” Tr. 2.37:14-21. The process generally requires a one and a half hour meeting three times a week for GI products. Tr. 2.34:8-11; Tr. 2.37:21-25.

40. The “purpose of the LMR review is to . . . ensure that the claims . . . are not misleading to consumers . . . [and] from a medical perspective [] are based on adequate substantiation.” Tr. 2.38:2-6.

41. The role of “legal” in the LMR process is “to look at any claims or messaging in the document” and make sure they “are not misleading and are supported by evidence.” Tr. 2.40:17-19.

42. The role of “regulatory” is to ensure that “the claims . . . are acceptable structure function claims based on DSHEA.” Tr. 2.40:22-25. If regulatory determines that a claim “is a disease claim,” it rejects the promotional material and no one can override that determination. Tr. 2.41:3-7.

43. The role of “medical” in the LMR process is to “look at dietary supplements and the claims [to] ensure that [there is] competent and reliable scientific evidence.” Tr. 2.39:9-15.

44. The Bayer medical group determines “the strength of the evidence” by looking to the “totality of evidence.” Tr. 2.44:16-18, 2.45:11-18; *see also* Tr. 2.38:16–2.39:8. The medical team “review[s] the literature in the public domain” and “look[s] at all the studies,” including those “related to the mechanism of action” “animal

studies” and “human data that may include randomized control[led] studies.” Tr. 2.44:18-19, 2.45:2-18.

45. The medical group “continu[ally] review[s] public domain data” on an ongoing basis, reviewing new studies around the time of their publication. Tr. 2.45:19 – 2.46:11, 2.9:4-10. They “keep abreast of the literature” by performing searches on scientific and medical databases (e.g., PubMed) and look at hundreds of articles per year. Tr. 2.45:19-23, 2.48:13-17. They do not “document or make note of or copy and paste every study” reviewed because it would not be “feasible” and because these studies are in their possession through access to the databases. Tr. 1.64:7-17, 2.49:2-12, 2.9:4-10, 2.52:8-13.

46. The medical representative determines whether the claims are substantiated based on available evidence. Tr. 2.36:15-2.37:4.

47. LMR “starts at idea generation” and approval is required before a product is launched. Tr. 2.42:22-25. As part of the LMR process for a new product, the medical team creates a “medical POV.” Tr. 2.43:1-9. The medical POV is based upon the “studies and literature from public domains, such as PubMed, Embase, Medline” as well as “proprietary data from suppliers.” Tr. 2.43:2-9. If there is “not much evidence” supporting a new product, then Bayer does not create a medical POV but produces a “one-page document [] summarizing the top line results of the data available.” Tr. 2.44:16-24. If there is a “vast amount of evidence” and sufficient substantiation to move forward the medical team creates a “full blown medical point

of view” file. Tr. 2.44: 16-24. The medical POV file describes the “strength of the evidence, the abundance of evidence and studies” that allows the company to move forward with the product. Tr. 2.43:2-9.

G. Scientific Substantiation for PCH

48. Bayer followed its LMR review process for PCH. Dr. Pana Beke explained that her predecessor Dr. Sefali Patel conducted a public literature search for probiotics and drafted a medical POV memo before launching PCH. PX-68 (Bayer HealthCare Consumer Care Division Point of View Memo: Probiotics for Gut and Immune Health, June 16, 2006 (“2006 POV Memo”)); *see also* Tr. 1.52:18-20. This POV memo documented Bayer’s first public literature search and review. PX-68. In a section entitled “literature review,” Dr. Patel explained that the “[l]iterature search resulted in an *abundant number of matches* for probiotic research in gut . . . health.” PX-68 at 3 (emphasis added). Dr. Patel uncovered such a “*vast number* of research material” that her “review was limited to encompass the last 6 years.” *Id.* (emphasis added). The memo proceeded to discuss over one dozen studies on gut/digestive health, that analyzed endpoints such as “constipation,” “gas,” “flatulence” “defecation frequency,” “colonic transit,” “irritable bowel syndrome,” “ulcerative colitis,” and “production of short chain fatty acids” PX-68 at 3-5. The memo was not an exhaustive list of all the studies Dr. Patel reviewed, but rather “reflect[ed] a sample of the studies that are” in the public domain.” Tr. 2.53:19-21.

49. The POV memo concluded that “[t]here is sufficient substantiation for the use of probiotics for gut or immune health.” PX-068 (2006 POV Memo) at 1.

50. After the POV Memo was drafted, the medical group continued to do public literature searches and to review data on a regular basis to determine that PCH’s claims were substantiated. Tr. 2.9:4-10 (“[W]e reviewed public domain data at the time [of launch in 2008]. We continue to review public domain data as we go on. That is what we do every single day.”).

51. Upon taking over the medical responsibility for PCH in 2009, Dr. Beke went “through the diligence of understanding the background for [PCH], understanding the probiotics, understanding the evidence . . . which included looking at all of the literature in the public domain . . . as well as the additional data that was shared . . . by . . . Wakunaga.” Tr. 1.53:8-16. Additionally, Dr. Beke further educated herself about probiotics by “talking to experts,” “talking to scientific people at [trade associations],” “really looking at the totality of evidence . . . to make sure that the claims for the product were adequately substantiated.” Tr. 1.53:8-24.

52. After she gained “a good understanding” of “the data, the evidence behind [PCH],” “the claims behind [PCH],” and “the medical POV,” Dr. Beke signed the medical POV affirming that in her medical opinion, the claims were substantiated. Tr. 1.116:15-25.

53. Dr. Beke did continuous reviews of the literature to stay up to date on the substantiation for PCH. Dr. Beke explained that she conducts a “weekly search”

in multiple scientific databases including PubMed, Embase and Medline. Tr. 2.18:2-15; Tr. 2.52:1-13. The search parameters included “the individual species with the benefit” of constipation, diarrhea, gas and bloating. Tr. 1.120:11-17; Tr. 1.71:20-25. These searches returned “hundreds of studies.” *Id.* Dr. Beke explained that this search process ensures that Bayer reviews and relies upon the published studies “at the time [they are] published.” Tr. 2.45:25. Therefore if a “study was published in . . . [she] would take a look at it around that time” of publication. Tr. 2.45:25-2.46:2. Since Dr. Beke took over responsibility for PCH, the scientific and medical evidence substantiating the claims for PCH “has strengthened.” Tr. 2.53:23-25.

54. Dr. Beke did not print out or make a separate record of the studies she reviewed and relied upon. Such a task would be impractical given that her group reviews over 60,000 studies each year. Tr. 1.121:1-5; *see also* Tr. 2.96:22-2.97:13 (Government witness stating that obligation to maintain documents does not require printing or filing documents). Instead, Bayer’s medical group reviews all of the scientific literature online and maintains access to the databases where that literature is published. In that way, Dr Beke and her colleagues possess the necessary substantiation and can locate, pull, and use the medical and scientific studies as needed. Tr. 1.68:18-1.69:3; *see also* Tr. 2.46:14-25.

55. PCH is primarily substantiated through studies done on the species of bacteria found in PCH. Tr. 2.54:18-23. Bayer produced nearly 100 of these studies to the FTC during the Government’s investigation. *See* Tr. 3.39:7-17.

56. All of the species level studies discussed by Dr. Beke and Bayer's experts at trial were part of the public domain studies that Dr. Beke reviewed and relied upon. Tr. 1.117:14-1.118:5. Contrary to assertions in the Government's closing argument, all but one of the studies discussed at trial was produced by Bayer to the FTC during the Government's investigation. DX-25, DX-30, DX-31, DX-32, DX-36, DX-167. The final study was produced during this litigation. These species-specific randomized controlled trials included:

57. Pitkala, et al. published "*Fermented Cereal with Specific Bifidobacteria Normalizes Bowel Movements in Elderly Nursing Home Residents: A Randomized, Controlled Trial.*" DX-36. This study demonstrated that the PCH species *Bifidobacterium longum* "had a significant effect in normalizing . . . bowel movements." DX-36; Tr. 6.100:9 – 6.101:16.

58. Margreiter, et al. published "*Therapeutic value of a Lactobacillus gasseri and Bifidobacterium longum fixed bacterium combination in acute diarrhea: a randomized, double-blind, controlled clinical trial.*" DX-32. This study was a "double-blind[] active control clinical trial [that was also] randomized." Tr. 6.102:24-6.103:1. The study showed that a combination of two species in PCH (*Lactobacillus gasseri* and *Bifidobacterium longum*) "shorten[] the duration and decreases the severity of . . . diarrhea in adults." DX-32; Tr. 6.101:23–6.102:16.

59. Guglielmetti, et al., published "*Randomised clinical trial: Bifidobacterium bifidum MIMBb75 significantly alleviates irritable bowel syndrome and improves quality of life – a*

double-blind, placebo-controlled study.” DX-26. This study was a “prospective, multi-centre, randomized, double-blind, placebo-controlled, two-arm nutritional study.” DX-26. The study showed that one of the species in PCH (*Bifidobacterium bifidum*) “significantly alleviates irritable bowel syndrome and improves quality of life.” DX-26; Tr. 6.103:15–6.104:25.

60. Guerra et al., published “*Pediatric functional constipation treatment with Bifidobacterium-containing yogurt: A crossover, double-blind, controlled trial.*” DX-25. This was a crossover, double-blind controlled trial. The study showed that one of the PCH species (*Bifidobacterium longum*) significantly improved constipation and abdominal pain. DX-25; Tr. 5.56:3–5.57:21.

61. Madden, et al., published “*Effect of probiotics on preventing disruption of the intestinal microflora following antibiotics therapy: A double-blind, placebo-controlled pilot study.*” DX-031. This study was a double blind placebo controlled clinical trial. The study showed an improvement in gut microflora and a better response to antibiotic therapy, often a cause of gastrointestinal issues. DX-31; Tr. 5.62:21–5.65:17.

62. There were also two strain-specific studies conducted by Wakunaga. The first, known as the Florida Study, showed “a positive impact in [its] primary outcome.” Tr. 6.108:16-21. The PCH product was proven to be beneficial for “maintenance” of gut homeostasis, which Dr. Fennerty described as digestive health and the absence of symptoms like constipation, diarrhea, gas and bloating. Tr. 5.74:1-5.

63. The second strain-specific study, known as the Canadian study, was “primarily a neutral study” but showed results that “trend[ed] positive” for digestive health benefits. Tr. 6.106:4-19. The study population was just over 100 people, and Dr. Fennerty explained that “[t]he study was underpowered” meaning there were “not enough people” to show a statistically significant benefit. Tr. 5.71:14-25. The study does not undercut Bayer’s substantiation of PCH because many successful products, including FDA-approved drugs, have neutral studies. *Id.*

64. Dr. Beke also possessed and relied upon proprietary data from Wakunaga (Bayer’s supplier for PCH). Tr. 1.53:8-24, 1.77:18 – 1.78:11; *see also, e.g.,* PX-69 (*Scientific Dossier of Probiotics Prepared Exclusively for Bayer Healthcare*).

H. Government’s Evidence

65. In its contempt motion, the Government for the first time disclosed the expert opinion of Dr. Loren Laine, who opined that competent and reliable scientific evidence for the PCH claims at issue requires a randomized controlled trial (“Laine-Level RCT”) meeting 8 specific requirements:

- (1) randomized,
- (2) placebo-controlled,
- (3) double-blind,
- (4) human clinical trial
- (5) done in the target population
- (6) with the specific product at issue,

(7) using appropriate statistical methods, and

(8) designed with the desired outcome as the primary endpoint.

Gov't Mot. for Contempt at 15-30.

66. Dr. Laine testified that only the “highest quality evidence,” Tr. 4.41:9-12, “level one evidence,” Tr. 4.40:23-4.41:1, or an “excellent” study of his design, Tr. 4.41:14-16, would satisfy the “competent and reliable scientific evidence standard.”

67. Dr. Laine admitted, however, that he had

- “never written any articles, books, or clinical guideline on probiotics;” Tr. 4.65:12-14;
- “never conducted a study of any kind on probiotics” Tr. 4.65:18-20; and
- is “not an expert in probiotics” Tr. 4.66:1-3

68. Dr. Laine does not “hold [himself] out as an expert on dietary supplements.” Tr. 4.67:16-18.

69. Dr. Laine does not “know of *any* probiotic product that has a study meeting [his] design.” Tr. 4.36:15-16 (emphasis added). In fact, he does not “know of *any* dietary supplement at all” that has a study meeting his design Tr. 4.36:20-22 (emphasis added).

70. Dr. Laine testified that his study design did not distinguish between drugs or supplements. Dr. Laine explained that his study design would apply equally

to “drugs,” “educational brochures,” “surgical interventions,” “supplements” and even “food.” Tr. 4.31:8-18; *see also* Tr. 4.31:19-23.

71. Similarly, Dr. Laine testified that his study design was not specific to probiotics or dietary supplements. He stated: “this clinical trial design[], is basically appropriate for *any situation* in which you want to obtain reliable results.” Tr. 4.31:19-23 (emphasis added). His required clinical study design is “not unique to GIs” but also would apply to other areas of medicine, including “ophthalmology” and “rheumatology.” Tr. 4.35:4-4.36:13.

72. The FTC did not provide Dr. Laine with a copy of the FTC Guidance for Industry regarding the substantiation necessary for dietary supplement claims. Therefore, Dr. Laine “did not rely on [the FTC Guidance] or look at it when [he] made [his] original report.” Tr. 4.16:4-5.

73. Dr. Laine also was not familiar with DSHEA, which regulates dietary supplements and categorizes supplements differently from drugs. Tr. 4.21:1-4. Dr. Laine “had not heard of the statute” at “the time that [he] provided [his] report.” Tr. 4.21:1-4.

74. Dr. Laine also “did not review [] or consider . . . FDA regulations in any way” in formulating his expert opinion. Tr. 4.23:13-16. Nor was Dr. Laine informed of the regulatory distinction between “structure function” claims and disease claims. 4.24:1-11.

75. Although Dr. Laine did “know in a general sense there has been a different interpretation [between the substantiation standards for dietary supplements and drugs]” he was “not up on the legal and regulatory issues as an expert.” Tr. 4.26:9-14. Dr. Laine admitted he was “not paying attention to the law or regulations about the difference between dietary supplements and drugs.” Tr. 4.26:16-20.

76. The Government presented no evidence of any law, regulation or guidance that would have provided notice to Bayer that Laine-Level RCTs are required for the PCH claims at issue. Tr. 2.59:4-8.

77. The Government presented no evidence that it had ever applied the Laine-Level RCT standard to any other probiotic or dietary supplement.

I. Bayer’s Experts

78. Bayer presented testimony from Dr. Daniel J. Merenstein. Dr. Merenstein is a professor of medicine and director of research programs at Georgetown University Medical Center, where he teaches classes on probiotics and clinical research. Tr. 6.8:14–6.9:5; DX-5-B (Dr. Daniel J. Merenstein CV) at 2. Dr. Merenstein is a leading expert on probiotics and has been a lead investigator on eight probiotic clinical trials, published multiple articles on probiotics, and has given national and international lectures to physicians and consumers about probiotics. Tr. 6.12:19–6.13:4; DX5-B (Merenstein CV) at 17-20.

79. Dr. Merenstein was part of the expert panel on probiotics convened by the International Scientific Association of Probiotics and Prebiotics (“ISAPP”) that

issued a report in 2014 titled, “*The consensus statement on the scope and appropriate use of the term probiotic.*” Tr. 6.13:5-21; DX-29 (“ISAPP Expert Consensus Report”).

80. As a physician, Dr. Merenstein “see[s] patients in a primary care setting,” where “[g]astrointestinal health issues” are “one of the primary things” he addresses. Tr. 6.9:11-21. Because probiotics are “one of the number one things we use for gastrointestinal issues,” they are used “quite often” and are “a regular part of primary care.” Tr. 6.10:3-7, 22-23. Dr. Merenstein has recommended various probiotic supplements, including PCH, “thousands of times” throughout his career. Tr. 6.10:16-23.

81. The Government presented no expert in probiotics, and Dr. Merenstein testified without contradiction regarding the expert consensus opinion on the benefits of probiotics for digestive health. Tr. 4.66:1-3, 4.67:16-18.

82. Dr. M. Brian Fennerty is a professor of medicine at the Oregon Health & Science University and a clinical researcher in the field of gastroenterology. Tr. 5.5:15-18; Tr. 5.10:5-10; DX-4-B (Dr. M. Brian Fennerty CV) at 1. He has “many hundreds of publications in th[e] field” of gastroenterology. Tr. 5.9:18-21. His clinical research has been published in *The New England Journal of Medicine*, *The Journal of the American Medical Association*, *The Annals of Internal Medicine*, and *Gastroenterology* - “some of the best scientific medical journals in the world.” Tr. 5.9:18–5.10:4. He has “been involved in the design and implementation and interpretation and conduct of many hundreds of clinical trials and studies.” Tr. 5.10:5-10.

83. Dr. Fennerty has done research on probiotics and the gut microbiome and has reviewed “[m]any hundreds, if not thousands” of studies on probiotics in his career. Tr. 5.8:24 – 5.9:7.

84. In his clinical practice as a gastroenterologist, Dr. Fennerty has recommended probiotics, including PCH, to his patients “[m]any hundreds, if not thousands of times.” Tr. 5.8:2-4. More specifically, he has “recommend[ed] probiotics that contain [L]actobacillus and [B]ifidobacter[ium], similar to the probiotics that are found in PCH,” to “help” his patients “maintain . . . digestive health.” Tr. 5.8:5-23.

85. Dr. Fennerty and Dr. Merenstein both testified that Dr. Laine is incorrect in suggesting that experts in the field would require Laine-Level RCTs to substantiate the PCH claims at issue. Tr. 5.108:3-4 (Dr. Fennerty testified that “a great, great majority, vast majority of my colleagues would disagree with Dr. Laine” that a Laine-Level RCT is required to substantiate the PCH claims), Tr. 5.27:16-21 (the view that a Laine-Level RCT is required for competent and reliable scientific evidence for the PCH claims is “very inconsistent with what the expectation is within the field of expertise [of] gastroenterology or . . . probiotics.”), Tr. 6.38:19 – 6.39:1 (“There is no question in [Dr. Merenstein’s] view and in the expert’s view in the field . . . , both probiotic and primary care experts,” that “the species-level RCTs” on “gasseri, bifidum, and longum . . . provide [substantiation for PCH claims] on their own” without the need for a Laine-Level RCT).

86. Dr. Fennerty and Dr. Merenstein testified that the published medical and scientific studies on the species of bacteria in PCH clearly substantiate Bayer's claims for PCH—both at the time of launch in 2008 and now. Tr. 5.80:2-9, 6.38:19–6.39:11.

87. Both Dr. Fennerty and Dr. Merenstein testified that PCH's claims are substantiated (both in 2008 and now) by the entire “hierarchy of scientific evidence” other than Laine-Level RCTs. Tr. 5.74:14-5.75:13, 6.20:10-6.23:8. They testified that biological plausibility, animal studies, in vitro studies, observational studies, epidemiological studies, human clinical studies, open label studies, randomized controlled trials on diseases, and randomized controlled trials on subpopulations all support Bayer's claims. Tr. 6.21; Tr. 5.40.

88. Dr. Fennerty and Dr. Merenstein testified that there are multiple “meta-analyses” showing that PCH claims are substantiated. Meta-analyses are “the highest level of evidence . . . definitely higher than [Dr. Laine RCTs],” Tr. 6.92:15-22, because “they put together more than one RCT” and minimize the probability that one was “lucky or unlucky in one study.” Tr. 6.92:2-12.

89. These meta-analyses include a Cochrane Report that concluded that “probiotics help reduce diarrhea” by analyzing “31 RCTs with nearly 4500 patients.” DX-167; Tr. 6.90:7-21. Dr. Merenstein testified that a meta-analysis such as the Cochrane Report is “clearly considered the highest level of evidence in medicine.” Tr. 6.90:14-15.

90. Another meta-analysis published in a pediatric journal concludes: “Given the totality of the evidence, additional placebo-controlled trials are unnecessary.” DX-49; Tr. 6.99:21-6.100:2.

91. Dr. Fennerty’s and Dr. Merenstein’s testimony is more credible than Dr. Laine’s testimony. Unlike Dr. Laine, both Dr. Fennerty and Merenstein understood that drugs and supplements “are entirely regulated differently.” Tr. 6.19:24-25. The evidence physicians consider “competent and reliable [evidence] is different for a disease state or a potentially hazardous treatment than it is in a healthy state” like a supplement. Tr 5.76:5-9.

92. Unlike Dr. Laine, both Dr. Fennerty and Dr. Merenstein understood the difference between structure function claims and disease claims. Dr. Merenstein was “quite familiar” with “FDA’s rules on structure function claims.” Tr. 6.12:13. Dr. Fennerty explained he does not “require the same level of proof of efficacy” for a supplement as he does for “a prescription drug.” Tr. 5.16:16-20.

93. Unlike Dr. Laine, both Dr. Fennerty and Dr. Merenstein were aware of and relied upon the FTC Guidance regarding dietary supplement substantiation in formulating their expert opinions in this case. Dr. Merenstein “relied on it heavily[,] it is very relevant.” Tr. 6.16:23. Dr. Fennerty explained “all of my opinions were made in reference to the [FTC] guidance [] document. I had no other way of coming to those opinions without this sort of guidance.” Tr. 5.13:5-7.

94. Unlike Dr. Laine, both Dr. Fennerty and Dr. Merenstein reviewed the totality of scientific evidence in reaching their opinions in this case. Tr. 6.22:2-7 (“when you evaluate the literature . . . you look at the totality” which includes “biological plausibility,” “animal data,” “bench research or in vitro research,” “epidemiological data,” and “clinical trials.”); *see also* Tr. 5.15:21-24.

II. Conclusions of Law

A. Standard of Review

95. The Government bears a “heavy burden to show . . . civil contempt,” *Fox v. Capital Co.*, 96 F.2d 684, 686 (3d Cir. 1938).

96. The Government must prove by clear and convincing evidence that the defendant violated a “clear and unambiguous provision of the consent decree.” *Harris v. City of Phila.*, 47 F.3d 1342, 1348 (3d Cir. 1995). “Specificity in the terms of consent decrees is a predicate to a finding of contempt, because [a defendant] will not be held in contempt . . . unless the order has given [it] fair warning.” *Id.* at 1349 (internal citation and quotation marks omitted). If the purported legal requirement cannot be “discern[ed]” from the “four corners” of the consent decree, the contempt action fails. *United States v. New Jersey*, 194 F.3d 426, 430 (3d Cir. 1999).

97. To “be placed at risk of contempt,” a defendant must be “given specific notice of the norm to which [it] must pattern [its] conduct.” *New Jersey*, 47 F.3d at 1349 (citing *Int’l Longshoremen’s Ass’n v. Phila. Marine Trade Ass’n*, 389 U.S. 64, 76 (1967)). Any “ambiguities and omissions in orders redound to the benefit of the

person charged with the contempt,” *Ford v. Kammerer*, 450 F.2d 279, 280 (3d Cir. 1971) (per curiam).

98. This Court interprets the consent decree “with reference to traditional principles of contract interpretation” and, therefore, “discern[s] the scope of a consent decree by examining the language within its four corners.” *New Jersey*, 194 F.3d at 430. “In so doing, [the court] must not strain the decree’s precise terms or impose other terms in an attempt to reconcile the decree with [the court’s] own conception of its purpose.” *Id.* (quoting *Harris v. City of Phila.*, 137 F.3d 209, 212 (3d Cir. 1998)).

B. Bayer Made Structure-Function Claims, Not Disease Claims

i. The Express Claims Made for PCH Are Structure-Function Claims

99. According to the FDA’s final rule on structure-function claims, Bayer’s claims for PCH (*see also supra* ¶¶ 26-36) are appropriate dietary supplement claims, called “structure-function claims,” not disease claims. *See* 65 Fed. Reg. 1000, 1006 (Jan. 6, 2000) (“a claim that a product ‘**helps promote digestion**’ would be a structure-function claim because it does not refer explicitly or implicitly to an effect on a disease state”); *id.* at 1026 (“for **relief of ‘occasional constipation**’ should not be considered [a] disease claim[]”); *id.* at 1031 (stating that “[a]lleviates the symptoms referred to as gas” and “[a]lleviates bloating” are structure-function claims “because the symptoms . . . are not sufficiently characteristic of specific

diseases”); *see also id.* at 1033 (“‘helps maintain regularity’ is an acceptable structure/function claim”); *see also id.* at 1015, 1029 (emphasis added).

100. The Government never asserted or presented any evidence that Bayer made disease claims under DSHEA and the Food Drug and Cosmetic Act. *See* 21 U.S.C. § 343(r)(6) (a claim that a product can “diagnose, mitigate, treat, cure, or prevent *a specific disease or class of diseases*” is a disease claim) (emphasis added).

101. Every package of PCH and every advertisement contains a disclaimer that that PCH is “not intended to diagnose, treat, cure or prevent any disease.” *See, e.g.* PX-2; Tr. 2.91:15-17.

102. The claims made for PCH are ubiquitous in the industry. *See, e.g.*, DX-243 (Align probiotic package) (“defense” and “defend against,” “ongoing protection from episodic: constipation, diarrhea, urgency, and gas and bloating,” “clinically proven to naturally defend against [constipation, diarrhea, urgency, and gas and bloating]”); DX-244 (Culturelle probiotic package) (“promotes better digestive health,” “helps your digestive system work better,” “helps reduce your digestive upset,” “helps with occasional diarrhea,” “helps with gas and bloating,”); DX-254 (Nature’s Bounty probiotic package) (“gas and bloating formula,” “patented strain to alleviate occasional gas and bloating” that has been “studied by gastroenterologists,” “advanced support for: gas and bloating” and “abdominal comfort”); DX-246 (PureLife probiotic package and bottle) (“gas and bloating prevention,” “helps digest,” “helps prevent occasional gas and bloating,” “relieves occasional abdominal

discomfort”); DX-247 (Activia probiotic advertisement) (“helping to regulate your digestive system,” “may help reduce the frequency of minor digestive issues like bloating, gas, discomfort and rumbling”).

103. The Government has not pointed to any instance when it has asserted that these claims are disease claims. If these claims were disease claims, then many of the most popular probiotic supplements on the market would be in violation of the law, and subject to seizure by the FDA.

104. The Court finds that the Government has failed to prove by clear and convincing evidence that Bayer made any express disease claims for PCH.

ii. There Are No Implied Disease Claims Made for PCH.

105. The Government has argued that Bayer made implied claims that PCH will prevent, treat, or cure constipation, diarrhea, gas and bloating. The Government has failed to prove by clear and convincing evidence that Bayer made such an implied claim.

106. The Government presented *no* evidence that Bayer made any implied disease claims. The Government offered no consumer survey data, no consumer testimony, no expert opinion on consumer understanding of the PCH ads, no marketing data, and no copy tests of any PCH advertisement. The FTC also made no factual findings regarding Bayer’s claims (unlike cases cited by the Government, *see Kraft, Inc. v. FTC*, 970 F.2d 311, 320 (7th Cir. 1992); *cf. FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 386 (1965)). Without evidence or an agency finding, the Court cannot

conclude by clear and convincing evidence that Bayer made any implied disease claims.

107. Even if Bayer made implied claims regarding prevention, treatment, or cure, they are not disease claims. Although the words prevent, treat, and cure often signal a disease claims, the Government has not proven that Bayer advertised PCH to prevent, treat, or cure *any disease*. Instead, the Government asserts that Bayer advertised PCH to prevent, treat, or cure constipation diarrhea, gas and bloating. These are not diseases, but rather variations of the normal state of health. *See* Tr. 5.16:23 – 5.17:6.

108. The Government has pointed to one—and only one— advertisement (a store display) that includes the phrase “prevention of occasional digestive upsets.” PX-120. Although the display uses the word “prevention,” it is not a disease claim. The use of the term “occasional” as well as the described symptom, “digestive upsets,” do not indicate a disease state; rather, this is a structure-function claim. *See* 65 Fed. Reg. 1000, 1006 (promotes digestion “does not refer explicitly or implicitly to an effect on a disease state”).

109. Further, every one of Bayer’s labels and advertisements contain the FDA disclaimer that PCH is “not intended to diagnose, treat, cure or prevent any disease,” *see supra* at ¶ 28, and a Government witness *conceded* that, with this disclaimer, Bayer “disclaim[ed]” any disease claim. Tr. 2.91:24.

110. The context of Bayer's ads confirms that there are no implied disease claims. *See* 65 Fed. Reg. at 1011 (in evaluating claim, must look at the overall "context in which the claim is presented"); *id.* at 1022, 1024-25, 1028, 1032 (same). Far from showing anyone "suffering from [a] disease," *id.* at 1012, Bayer's advertisements display active healthy people playing golf, riding a tour bus, going on a safari, or getting on an airplane. *See, e.g.,* PX-157, -158 (ad showing PCH spokeswomen speaking to active and healthy individuals on a safari); PX-34, -41 (ad showing PCH spokeswomen speaking to active and healthy individuals on an airplane); PX-23, -25 (ad showing PCH spokeswomen speaking to active and healthy individuals at a book reading). And the ads do not involve a doctor or nurse, but the PCH spokesperson, referred to as the "Colon Lady," who is giving humorous wedding speeches about bloating, performing dramatic readings in book stores, and preaching about gas on street corners. Tr. 2.98:10-20 (Government witness affirming that the advertisements "made [her] laugh"). As a Government witness testified, "[n]one of [PCH's] advertisements show sick people." Tr. 2.98:4-5. "None of those advertisements show[] anyone suffering from a disease," Tr. 2.98:7-9, let alone "clearly and conspicuously," *F.T.C. v. National Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (2008).

111. For the foregoing reasons, the Court cannot find by clear and convincing evidence that Bayer made an implied disease claim.

C. Bayer Was Not Provided With Any Notice That The Consent Decree Requires a Laine-Level RCT

112. To prove contempt, the Government must show by clear and convincing evidence that Bayer violated a “clear and unambiguous provision of the consent decree.” *Harris*, 47 F.3d at 1348. If there is ambiguity or doubt, there can be no contempt. *Ford*, 450 F.2d at 280. If the purported legal requirement cannot be “discern[ed]” from the “four corners” of the consent decree, the contempt action fails. *Harris v. City of Phila.*, 137 F.3d 209, 212 (3d Cir. 1998) (citing *United States v. Armour & Co.*, 402 U.S. 673, 681-82 (1971)). The Government does not meet this standard.

113. As two other courts have held, competent and reliable scientific evidence does not require drug-level clinical trials, and the Government cannot try to reinvent this standard through expert testimony. *FTC v. Garden of Life Inc.*, 845 F. Supp. 2d 1328, 1334-35 (S.D. Fla. 2012) (When a consent decree speaks only of “competent and reliable scientific evidence,” the Government cannot redefine it through expert testimony and “require [the] court to read additional requirements into the Consent Decree.”), *aff’d in part and vacated in part*, 516 F. App’x 852 (11th Cir. 2013); *Basic Research, LLC v. FTC*, No. 2:09-cv-0779 at 26-27 (D. Utah Nov. 25, 2014) (By demanding “gold standard” clinical trials, which “exceed[] the requirements of the [consent decree],” the Government failed the “expectation of reasonableness.”).

114. The Government's position that Laine-Level RCTs are required is found nowhere within the four corners of the consent decree, but only within the expert report that was filed with the Government's motion for contempt. The Consent Decree that Bayer agreed to in January of 2007 speaks only of "competent and reliable scientific evidence." DX-1. The Consent Decree does not mention randomized controlled clinical trials of any kind, let alone say they are required. *Id.* In the seven years after entering the Consent Decree, the Government never told Bayer or anyone else in the industry that drug-level clinical trials or Laine-Level RCTs were required.

115. Counsel for the Government conceded in closing argument that "you have to go outside of the four corners of the consent decree" in order to find support for the Government's standard. Tr. 7.61:3-4.

116. Because the definition of "competent and reliable scientific evidence" looks to the view of experts in the relevant field, it is appropriate for the Court to consider the testimony of experts in the field. *See, e.g. FTC v. Lane Labs-USA, Inc.*, 624 F.3d 575, 582 (3d Cir. 2010). (A consent decree does not need to delineate the specific scientific substantiation necessary for every conceivable claim.) But, for there to be contempt, the legal standard must be "clear and unambiguous." *Harris*, 47 F.3d at 1348. The government cannot seek contempt on the basis of a lone expert who proposes a standard that was not disclosed to industry until the day the government filed its contempt motion.

117. This is especially true where, as here, that testimony is inconsistent with the agency's own guidance. The FTC has issued Guidance which provides scientific and medical advice regarding the meaning of competent and reliable scientific evidence. That Guidance specifically refutes the standard the Government is seeking to impose. According to the FTC Guidance: "There is no fixed formula for the number or type of studies required . . ." FTC Guidance PX-1 at 9. Moreover, "[t]here is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine." *Id.* at 12. In fact, "[t]he FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science" *Id.* at 8

118. The Government has entered into consent decrees with other companies in which it required "two adequate and well-controlled human clinical studies," that "shall be randomized . . . double-blind and placebo-controlled." DX-239 (2010 Dannon Co., Inc., Consent Decree), Definitions ¶ 3, § II; DX-240 (2010 Nestle HealthCare Nutrition, Inc., Consent Decree), Definitions ¶ 3, § II; DX-241 (2010 Iovate Health Sciences USA, Inc., Consent Decree), Definitions ¶ 4, § II; DX-242 (2012 Jason Pharms., Inc., Consent Decree), Definitions ¶ 1, § II.

119. Likewise, in *POM Wonderful LLC*, 777 F.3d 478, 497 (D.C. Cir. 2015), the consent decree provision at issue explicitly required "randomized and controlled human clinical trials." *Id.* The D.C. Circuit expressly distinguished that provision, which pertained to "*disease-related*" claims, from another provision, which pertained

to “more general claims about health benefits.” *id.* (emphasis in original). This other provision required only “competent and reliable scientific evidence,” *not* “randomized, controlled, human clinical trials support.” *Id.*; *see also id.* at 501 (“In short, Part III’s baseline requirement for all health claims *does not require RCT substantiation*, whereas the specific requirements in Part I for disease-related claims not only contemplate RCT substantiation, but call for — as a categorical matter—two RCTs”) (emphasis added); *id.* at 504 (“[S]everal orders over the past decade require *only ‘competent and reliable scientific evidence’—not necessarily RCTs*, let alone two RCTs—to substantiate disease claims akin to those made by petitioners.”) (emphasis added).

120. These examples show that when the Government wants to require RCTs, it knows how to do so. The Government cannot enter into a consent decree using the general competent and reliable scientific evidence standard and then subsequently require RCTs through the expert testimony it produces in a contempt action.

121. The Government identifies only one case in which any court has held that RCTs are required under the competent and reliable scientific evidence standard. *See* Dkt. No. 186 at 75 (citing *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957–58 (N.D. Ill. 2006)). The Government fails to disclose that this holding by a magistrate judge was expressly rejected on appeal by the Seventh Circuit. Although the Seventh Circuit affirmed the judgment, the panel made clear that “[p]lacebo-controlled, double-blind testing is not a legal requirement for consumer products.” *Id.* at 861; *see also id.*

(“Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies.”). Although “[a] placebo-controlled, double-blind study is the best test; *something less may do.*” *Id.* at 862 (emphasis added). The Seventh Circuit affirmed the judgment only because the defendant’s tests were “bunk,” not because the defendant failed to have a placebo controlled clinical trial. *Id.*

122. The plain language of the 2007 Consent Decree does not give Bayer any notice that Laine-Level RCTs are required for its probiotic claims or any dietary supplement claims. To interpret the plain language to include the additional requirement of an 8-part Laine-Level RCT—which the government did not disclose until it sought contempt—would improperly “strain the decree’s precise terms or impose other terms.” *United States v. New Jersey*, 194 F.3d at 430 (quotation marks omitted).

D. Dr. Laine’s Testimony Does Not Satisfy the Government’s Burden

123. Even putting aside the lack of notice, the Government has not met its burden to show that Bayer is in contempt. The Government argues that the Consent Decree looks to what experts in the field require for substantiation, that Dr. Laine is an expert in the field, and that Dr. Laine requires Laine-Level RCTs. But, Dr. Laine’s testimony does not meet the Government’s burden.

124. First, Dr. Laine lacks the expertise necessary to prove what experts in the field would require. *See supra*, ¶¶ 67-69 (Dr. Laine admitted he is “not an expert in probiotics” and has limited experience in probiotics). A gastroenterologist who is

not an expert in probiotics and does not regularly use them in his practice is not in a position to testify as what type of evidence experts in the relevant area require. DX-1 at 2.

125. Second, Dr. Laine's opinion cannot be reconciled with the legal and regulatory standards that govern the substantiation of dietary supplement claims.

126. Dr. Laine had no familiarity with the statute, DSHEA, that regulates dietary supplements and treats supplements differently from drugs. Tr. 4.21:1-4

127. Dr. Laine "did not review or consider FDA regulations in any way" in formulating his expert opinion. Tr. 4.23:13-16. Dr. Laine was not aware of the distinction between "structure function" claims for dietary supplements and disease claims for drugs. Tr. 4.24:1-11. Dr. Laine admitted he was "not paying attention to the law or regulations about the difference between dietary supplements and drugs" in formulating his opinion. Tr. 4.26:16-20.

128. Dr. Laine testified that his opinion makes *no* distinction between "drugs" and "supplements" (or even "educational brochure[s]," "surgical intervention[s]," and "food.") Tr. 4.31:8-18; *see also* Tr. 4.31:19-23 (agreeing that his "clinical trial design[] is basically appropriate for *any situation* in which you want to obtain reliable results . . . for those . . . symptoms.") (emphasis added).

129. This is directly contrary to DSHEA, in which Congress expressly recognized "the benefits of dietary supplements to health," eliminated the pre-

approval requirement that applies to drugs, and lowered the substantiation requirement for dietary supplements, 21 U.S.C. § 343(r)(6).

130. The Government did not provide Dr. Laine with the FTC Guidance that defines what substantiation is necessary for dietary supplement claims. Dr. Laine “did not rely on [the FTC Guidance] or look at it when [he] made [his] original report.” Tr. 4.16:4-5. Dr. Laine’s opinion is contrary to the FTC Guidance. For example, Dr. Laine “testified . . . that there is a specific study design or protocol that . . . should be followed to substantiate [PCH].” Laine Tr. 4 27:10-15. The FTC Guidance, by contrast, provides that there is “no fixed formula” and “no set protocol.” FTC Guidance PX-1 at 12. Similarly, Dr. Laine opined that any study relied upon by Bayer must be done on the exact three strain product and in the exact population that the product is marketed to. Tr. 4.13:6-21. The FTC Guidance, however, permits companies to use tests done on a “similar formulation” and permits companies to “extrapolate” between populations. FTC Guidance at 15-16; *see supra* ¶¶ 12-14 (listing inconsistencies between Dr. Laine opinion and FTC Guidance).

131. Third, contrary to the assertion of Government counsel, Dr. Laine’s testimony does not reflect the opinion of experts in the field. The opinion Dr. Laine offered was a personal opinion that he did not share with any other expert or physician. Tr. 4.64:18-22. The government presented no evidence that any other expert agreed with Dr. Laine’s opinion. Dr. Fennerty’s testified that few, if any, relevant experts would agree with Dr. Laine:

I respect Dr. Laine's declaration, and I read it carefully, and I gave it a lot of consideration. But not only myself, I think a great, great majority, vast majority of my colleagues would disagree with Dr. Laine here I just don't agree with him, and I don't see where other experts in the field would agree with him."

Tr. 5.108:1-8.

132. Fourth, Dr. Laine's standard conflicts with the longstanding understanding of substantiation requirements in the industry. Although the claims Bayer makes for PCH are the same exact claims made by many other probiotics on the market today, *see, e.g., supra* ¶ 102, *none* has a study that meets Dr. Laine's standard. Tr. 4.36:15-19; Tr. 5.26:1-7; Tr. 6.115:9-13.

133. Fifth, Bayer presented evidence from Dr. Merenstein and Dr. Fennerty showing that experts in the relevant fields do not require Laine-Level RCTs to substantiate probiotic supplement claims. Both Dr. Merenstein and Dr. Fennerty understood and relied upon the FTC Guidance and the distinction it draws between supplements and drugs in formulating their expert opinions. Tr. 6.12:14-18; Tr. 5.16:16-20; Tr. 6.16:23-25; Tr. 5.13:13-17.

134. Dr. Merenstein, the only expert in probiotics that testified in the case, stated: "Dr. Laine's RCTs are clearly . . . not a requirement for a supplement," and "[i]t's clear they are not required" to demonstrate the efficacy of probiotics. Tr. 6.23:1-3, 6.31:13-18.

135. Dr. Fennerty also testified as an expert gastroenterologist and clinical researcher: Dr. Laine's RCT "is a superb study design, but I disagree that it is necessary for substantiation in this case." Tr. 5.26:1-8, 5.25:9-11.

136. Neither Dr. Fennerty nor Dr. Merenstein could identify, after research, a single probiotic or a single dietary supplement on the market that possessed a study design meeting Dr. Laine's criteria. Tr. 6.115:9-10 ("[No] product currently on the market [] has a study that meets Dr. Laine's design."). Dr. Laine could not identify one either. Tr. 4.36:15-17; Tr. 4.36:20-24.

137. Dr. Merenstein has done RCTs but *none* that would meet Dr. Laine's test. Tr. 6.70:5-6 ("They had some similarities, but they are not Laine-Level RCTs").

138. Sixth, Dr. Laine's testimony is contradicted by the Expert Consensus Report by ISAPP, on which he relied. Far from requiring Laine-Level RCTs, the Expert Consensus Report concluded that RCTs were *not* required for probiotic claims concerning digestive health. Tr. 6.65:19-6.66:2 ("To determine whether an association exists between a substance (such as a probiotic) and a desired outcome (such as maintain a healthy digestive system), it is important to examine the following criteria: temporal relationship . . . biological plausibility . . . dose response . . . replication of findings" and other non-RCT data). The report stated that probiotics should be subject to the same standard applied to other dietary supplements, such as vitamins C and calcium, neither of which is supported by a RCT on a healthy population. Tr. 6.66:12-14 ("probiotic foods or supplements should not be held to a high[er] standard

of evidence than other foods or supplements”); Tr. 6.66:19-20 (“no robust RCTs in healthy individuals supporting these benefits” on vitamin and calcium).

139. The Expert Consensus Report further concluded that the “panel [was] convinced that sufficient evidence has accumulated to support the concept of ‘core’ [*i.e.*, gastrointestinal health] benefits of certain probiotics,” including the species in PCH. ISAPP Report at 3; *see also* Tr. 6.56:9-15, 6.84:18-22 (panel’s conclusion that the species of *Lactobacillus gasseri*, *Bifidobacterium bifidum*, and *Bifidobacterium longum* provide a core benefit for digestive health issues including constipation, diarrhea, gas and bloating was “unanimous.”).

140. Finally, some of the factual and scientific underpinnings of Dr. Laine’s opinion are inaccurate. For example, Dr. Laine testified that species of bacteria combined in one product “could be antagonistic.” Tr. 3.63:21-22. Dr. Fennerty explained that the idea that probiotics could be antagonistic “is contrary to what I think most experts in the field would state, including myself;” there is no “biological plausibility” and no “evidence” for Dr. Laine’s suggestion. Tr. 5.80:15-23. Dr. Merenstein explained that he “wholeheartedly disagree[s]” with Dr. Laine’s statement that probiotics could be antagonistic. Tr. 6.74:21. He said: “[Dr. Laine] cites nothing for that . . . because there’s no references. There is no possibility. There’s no one that believes that they are antagonistic. It makes no sense.” Tr. 6.75:8-11.

141. Dr. Laine also mischaracterized the extent to which existing probiotic studies are “positive” for digestive health benefits. In response to the Court’s

question whether “there [were] any positive studies,” Dr. Laine responded “there were some [but] [i]t was the minority.” Tr. 3.71:7-20. Although it is unclear whether Dr. Laine was referring to the studies Bayer produced to the Government or the studies in the public domain, it is clear that Dr. Laine’s statement was wrong. No study (produced to the Government or in the public domain) is negative. Tr. 5.50:8-15. Dr. Merenstein testified that this assertion by Dr. Laine was “entirely incorrect” and that the “mass majority [are] positive.” Tr. 6.35:12-16; Tr. 6.35:25. Dr. Fennerty corroborated that “the majority of them are positive studies.” Tr. 5.51:6-7. Although some studies are null (meaning they show no statistically significant benefit), *none* shows negative results. *See id.*; *see also* Tr. 7.74:20-7.75:5.

E. Bayer Possessed and Relied Upon Competent and Reliable Scientific Evidence

142. Although Bayer has no burden in this litigation, the evidence presented by Bayer at trial established that it possessed and relied upon competent and reliable scientific evidence for its claims for PCH.

i. Bayer Possessed and Relied Upon Evidence From The Public Domain, As Well As Proprietary Data

143. Bayer presented testimony and documents demonstrating the scientific studies it possessed and relied upon to support its claims for PCH. The Government asserts that the Court should infer that Bayer did not possess or rely upon any such studies because Bayer did not print out, copy, or otherwise record all of those studies. But, the Consent Decree does not require Bayer to make records or copy studies.

Bayer's only obligation was to possess and rely upon competent and reliable scientific evidence. To possess and rely upon a scientific study, Bayer need not copy it from an electronic database that Bayer already possesses and put it in a filing cabinet.

144. The parties to consent decrees are bound by words' "objective definition[s]." *United States v. New Jersey*, 194 F.3d at 430 (quoting *In re Unisys Corp. Long-Term Disability Plan ERISA Litigation*, 97 F.3d 710, 715 (3d Cir. 1996)); *see also Unisys*, 97 F.3d at 715 ("[C]ommon words of accepted usage . . . should be interpreted in accord[ance] with [that] usage unless such an interpretation would produce irrational results.") (quotation omitted). In ordinary usage, Bayer can "possess" scientific evidence for its claims without creating an electronic or paper copy of each study.

145. The dictionary definition of "possess" extends to knowledge or mastery of intangible information. To possess is "to have knowledge of," *Random House Webster's Unabridged Dictionary* 1509 (2d ed. 2001), "to have knowledge or skill in," *Webster's Third New International Dictionary* 1770 (1993), "[t]o acquire command of or have knowledge of," *The American Heritage College Dictionary* 1087 (4th ed. 2004), or "to have mastery or knowledge of: . . . *possess valuable information*," *The American Heritage Dictionary* (5th ed. 2011).

146. Courts frequently describe an actor who knows legally relevant facts as "possessing" evidence, information, or knowledge, regardless of whether those facts are memorialized in tangible form. *See Whiteley v. Warden*, 401 U.S. 560, 566–67 (1971)

(noting that the arresting officer “possessed” information and knowledge from a bulletin heard on the radio, from personal observation of the suspect’s vehicle, and from his partner’s knowledge of the suspect’s name); *Merkle v. Upper Dublin Sch. Dist.*, 211 F.3d 782, 790 (3d Cir. 2000); *California v. Trombetta*, 467 U.S. 479, 485 (1984) (“[The government] may be required to disclose the identity of undercover informants who possess evidence critical to the defense.”); *United States v. Valenzuela-Bernal*, 458 U.S. 858, 861 (1982) (describing the government’s decision to deport aliens after “conclud[ing] that the passengers possessed no evidence material to the prosecution or defense of respondent”).

147. Dr. Pana Beke, the current medical lead for PCH testified that Bayer reviewed and relied upon the scientific studies in the public domain. Bayer first obtained studies in the public domain before launching the product when the medical lead at the time, Dr. Sefali Patel, drafted a medical POV file for PCH. PX-068; *see also supra* ¶¶ 48-53 (discussing Bayer’s medical POV that recorded Dr. Patel’s first public literature search). Dr. Beke also testified that Bayer possessed and relied upon proprietary studies from Wakunaga. Tr. 1.53:8-24, 1.77:18–1.78:11.

148. Even after Dr. Patel finalized the 2006 POV Memo, the medical group reviewed data in the public domain on an ongoing basis to evaluate substantiation. *See supra* ¶¶ 48-53. Upon taking over as the medical lead when Dr. Patel left Bayer for a position at another company, Tr. 2.40:3-9; Tr. 2.43:17-20, Dr. Beke continued to conduct public literature reviews to obtain scientific studies related to the claims for

PCH. Tr. 2.9:4-10. This search process ensured that Bayer reviewed and relied upon the published studies “at the time [they were] published.” Tr. 2.45:25.

149. There is no basis to conclude that the absence of electronic or physical records should give rise to an inference that Bayer did not possess and rely upon competent and reliable scientific evidence. First, any such inference is contrary to the uncontradicted testimony of Dr. Beke that Bayer did in fact possess and rely upon the scientific studies in the public domain. Dr. Beke’s testimony was corroborated by the POV memo and by the testimony of Drs. Merenstein and Fennerty about what information is in the public domain. *See supra* ¶¶ 48-53.

150. Second, no inference should be drawn from the lack of physical records, because the recordkeeping provision of the Consent Decree did not require Bayer to print out documents in the public domain. The recordkeeping provision required Bayer to “maintain” documents, and as the Government witness testified, the obligation to “maintain” documents “does not mean create.” Tr. 2.96:22-2.97:4. It does not require a company “to print out stuff that [it] see[s] on the internet.” Tr. 2.97:5-13.

151. Third, the Government never told Bayer in the seven years since entering into the Consent Decree that it was required to copy or print out the studies it reviewed on public databases. Tr. 1.121:1-5. The Government did not even raise this issue in its contempt motion or any other brief prior to its trial brief. Dkt. No. 158.

152. For purposes of compliance with the terms of the Consent Decree, it was sufficient that Bayer relied upon studies it accessed on medical and scientific databases that were in its possession.

ii. Bayer's Evidence Satisfies the Competent and Reliable Scientific Evidence Standard

153. Bayer's experts Dr. Merenstein and Dr. Fennerty reviewed the evidence Bayer possessed and relied upon at two points in time. First, they reviewed the evidence in the public domain and the Wakunaga proprietary data that was available at the time the product launched in 2008. Tr. 5.74:14-23, 6.105:8-14. Second, they looked at the evidence available in the public domain and the proprietary Wakunaga data available now. Tr. 5.74:24–5.75:13, 6.105:1-14.

154. Dr. Merenstein testified that in his expert opinion, the evidence available at the time of launch in 2008 provided competent and reliable scientific evidence for Bayer's claims. Tr. 6.39:5-16 ("Species level RCTs in 2008 on their own provide[d] competent and reliable scientific evidence for the claims at issue.")

155. Dr. Fennerty likewise testified that in his expert opinion, the evidence available at the time of launch in 2008 provided competent and reliable scientific evidence for Bayer's claims. Tr. 5.74:17-23 ("I know there was competent and reliable scientific information available in 2008, and in order to make sure my recollection was correct, I repeated a search . . . up to 2008, and there were hundreds of publications

substantiating the claims that were available in the scientific literature and the public domain in 2008.”).

156. Dr. Fennerty testified that the scientific substantiation has become more robust over time and that the public data currently available provides competent and reliable scientific evidence for Bayer’s claims. Tr. 5.47:2–5.48:4; Tr. 5.74:24–5.75:13.

157. Dr. Merenstein testified that the current scientific evidence provides competent and reliable scientific evidence for Bayer’s claims. Tr. 6.105:1-14.

158. The Government has misleadingly cited testimony from Dr. Pana Beke where she states that Bayer does not have substantiation for *disease* claims. However, Bayer has not made disease claims. *See supra* ¶¶ 26-36. Dr. Beke made clear that she believes that “we do have, as I said, competent and reliable scientific evidence to support each claim that we currently made and have made in the past for PCH.” Tr. 1.113:9-12.

159. The Wakunaga data further supports Bayer’s claims, but both Dr. Merenstein and Dr. Fennerty testified that the public data on its own provides competent and reliable scientific evidence for Bayer’s claims.

160. Numerous expert groups confirm there is competent and reliable scientific evidence for Bayer’s claims.

161. The Priority Update from Research Literature (PURLs), a publication by the University of Chicago that issues updates written by experts in the field of family medicine and is a “great source in primary care,” gave probiotics an evidence of grade

“A” for their use in preventing antibiotic-associated diarrhea, a common cause of diarrhea. Tr. 6.85:15-6.87:14. The PURLs report directs practicing physicians to recommend probiotics including Bifidobacteria and Lactobacillus to their patients for diarrhea. *Id.* Notably, an “A” rating from PURLs does not come lightly; PURLs gave only a “B” ranking for evidence of the coronary benefits of physical exercise. Tr. 6.87:10 – 6.88:22.

162. The Expert Consensus Report published by the International Scientific Association for Probiotics and Probiotics also confirms that Bayer’s claims are substantiated. As an author of the report, Dr. Merenstein, stated: “[O]ne of the take home points” of the ISAPP Expert Consensus Report was that “you can make these claims about gastrointestinal health,” including “symptoms of occasional constipation, diarrhea, gas and bloating that are at issue in this case,” for the “core species.” Tr. 6.55:6-11. Unlike the “core” benefit of digestive health, the Expert Consensus Report would still require strain-specific evidence for other potential benefits of probiotics, such as skin health or neurological health .

163. Dr. Fennerty testified that the ISAPP Expert Consensus Report confirms that strain specificity is not required for the core benefit of digestive health: “[W]hen it comes to core benefits of digestive health, evidence is sufficient at the[] species level, and strain specificity is not required.” Tr. 5.44:18-22. Dr. Laine conceded that the “ISAPP consensus report affirms that the ability to impact digestive health is not a strain specific characteristic.” Tr. 4.61:16-18. Digestive health is

defined by the American Gastroenterology Association in reference to the symptoms at issue: the absence of frequent constipation, diarrhea, gas and bloating. DX-251 at 2-3; Tr 6.09:25-6.10:2; Tr. 5.23:6-7; Tr. 4.56:25.

164. The Government has pointed to a 2011 publication that Dr. Laine did not review or consider. Tr. 6.83:11-13. According to the Government, this article shows that strain-specific evidence is required. However, as Dr. Merenstein testified, this article discusses “allergy,” “immune response,” and other symptoms that are not related to the “core benefit of digestive health”; it is not speaking strictly about digestive health. Tr. 6.234:6-19.

F. Bayer Substantially Complied

165. Finally, even if the Government could show that Bayer violated the Consent Decree, the Court does not hold Bayer in contempt because Bayer “substantially complied” with the Consent Decree

166. A party cannot be held in contempt when it “substantially complies” with a court order. *FTC v. Lane Labs U.S. Inc.*, 624 F.3d 575, 591 (3d Cir. 2010).

167. “A party substantially complies when it takes all reasonable steps to do so, but nonetheless contravenes the court order by good faith mistake or excusable oversight.” *Id.* at 590.

168. Bayer took extensive steps to comply with the Consent Decree. Bayer had an extensive LMR process that reviewed every single piece of promotional material for compliance with the Consent Decree. Tr. 2.34-2.36.

169. Bayer also acted in good faith. Bayer believed in good faith that it possessed and relied upon substantial scientific evidence to support the claims for PCH.

170. Because the alleged failure to have Laine-Level RCTs was not disclosed until the contempt motion was filed, Bayer's failure to have Laine-Level RCTs is, at worst, a technical, inadvertent, and good faith mistake.

171. This Court finds that Bayer substantially complied with the Consent Decree.

CONCLUSION

For the foregoing reasons, the Court DENIES Government's motion for contempt.

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